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TITLE: Ovarian Cancer Risk and Survival in BRCA 1/2 Carriers

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CONTRACTING ORGANIZATION: University of Pittsburgh  
Pittsburgh, Pennsylvania 15260

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<b>13. Abstract (Maximum 200 Words) (abstract should contain no proprietary or confidential information)</b> This project is evaluating whether oral contraceptives and parity are as protective against ovarian cancer in BRCA1/2 carriers as they are for women in general. It is also determining whether there are survival differences between BRCA1/2 carriers with ovarian cancer compared to women with sporadic disease. The study employs a case-case design. We will identify about 400 Jewish women with epithelial ovarian cancer. We will genotype these women for the 3 BRCA1/2 mutations found in Ashkenazi women. We will then compare oral contraceptive use and parity between carriers and non-carriers. We will also compare survival differences between the two groups. In the first year of the project, we have identified 36 eligible subjects. Risk factor data and pathologic specimens have been obtained on these women. Using the pathology specimens, we have genotyped the 36 subjects and identified 17 mutation carriers. To date, we are on schedule to complete this project as outlined in the original Work Plan.				
<b>14. Subject Terms (keywords previously assigned to proposal abstract or terms which apply to this award)</b> prevention, chemoprevention, epidemiology, molecular epidemiology, etiology, BRCA1/2, risk factors, oral contraceptives, parity, survival			<b>15. NUMBER OF PAGES</b> 33	
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## **INTRODUCTION:**

The goal of this project is to determine whether oral contraceptives (OCs) and parity are as protective against ovarian cancer in BRCA1/2 carriers as they are for women in general. The second goal is to determine whether there are survival differences between BRCA1/2 carriers with ovarian cancer compared to women with sporadic disease. The study employs a case-case design. We will identify about 400 Jewish women with epithelial ovarian cancer. We will genotype these women for the 3 BRCA1/2 mutations found in Ashkenazi women. We will then compare oral contraceptive use and parity between carriers and non-carriers. We will also compare survival differences between the two groups.

## **BODY:**

In this section, we describe our accomplishments according to the Work Plan originally approved. Accomplishments are shown in *italics*.

### *Task 1 Preparation for Study, Months 1-6:*

- a. Any remaining IRB approvals will be obtained
  - *All IRB approvals have been obtained. Specifically, we have obtained approval from North Shore University Hospital, which houses approximately 50% of the study samples (see attached letter in the Appendix).*
- b. The Medical Record Abstraction form will be tested on a subset of subjects and revised accordingly
  - *We tested the form and in conjunction with Dr. Edwards, the project gynecologic oncologist, we have updated it*
- c. A study database will be designed and relevant data from previous studies will be downloaded
  - *We have designed the study database*
  - *Relevant data from the SHARE study was downloaded on the 36 subjects identified as Jewish in the parent study and for whom pathologic specimens were obtained*
- d. A study key will be created
  - *A study key was created and is maintained by Dr. Nelson at the University of Pennsylvania*

### *Task 2 Performance of Laboratory Assays, Months 1-28:*

- a. Specimens (400) will be located, cut, labeled with the new study ID and shipped to the core lab
  - *36 specimens were located, cut, labeled with the new Study ID and shipped to Dr. Kant's Laboratory (the project genotyping laboratory).*

- b. Assays (400) to detect *BRCA1/2* mutations will be performed and the results recorded on study forms
  - *The 36 specimens were genotyped for the 3 Ashkenazi mutations. Among the 36 subjects, we found 17 mutations carriers.*
- c. A subset of specimens (80) will be retested to validate the laboratory results
  - *10 specimens were retested to confirm genotyping results. All retests agreed with the original assay results, providing assay validity.*

**Task 3 Preparation for Medical Record Abstraction and Data Entry, Months 6-12:**

- a. The Medical Record Abstraction form will be finalized and the investigator trained to perform patient data reviews using the instrument
  - *The form was finalized and we are training the North Shore University Hospital Investigator, the site with the largest number of subjects, to perform the abstraction*
- b. The computerized data entry form for medical record data will be designed and implemented in PoP
  - *The form was implemented using TELEform, an automated data entry system. We chose TELEform instead of the PoP system as originally proposed because TELEform supports automated data entry and should greatly diminish the time for and increase the accuracy of data entry required by this project.*
- c. The computerized data entry form for laboratory assay data will be designed and implemented in PoP
  - *Because this form is so simple, Dr. Kant's Laboratory employs a Microsoft Excel form for data entry. We have decided that this is sufficient and compatible with our data entry system.*

In addition, although not listed in the Work Plan, we hired a part time project manager (Pam Overberger, MS) to oversee the work, including obtaining specimens, maintaining IRBs, implementing the data entry forms in TELEform, implementing the study database and generating preliminary reports.

**KEY RESEARCH ACCOMPLISHMENTS:**

Because this is the first year of the project, our data analyses are preliminary and limited to the 36 subjects that we genotyped for the 3 Ashkenazi mutations. Our results are as follows:

Mean age at diagnosis:	54.6 years
Family History of Ovarian Cancer:	6
Nulliparous	8
No. Live births (among parous women)	1.9

OC use	16
OC duration (among users)	3.5 years
Mutation Carriers	17

Because of the small numbers, we did not do any further analyses, nor did we compare carriers to non-carriers. Such results at this point would be meaningless. Nonetheless, these data provide evidence of our accomplishments to date: identifying eligible participants and pertinent data, obtaining specimens, and genotyping specimens.

#### **REPORTABLE OUTCOMES:**

No reportable outcomes have been obtained thus far. We anticipate a preliminary manuscript describing the OC and parity endpoints next year.

#### **CONCLUSIONS:**

In conclusion, this project is on target to complete the work as outlined in the Work Plan. We anticipate providing data on the role of OCs and childbearing on the risk of ovarian cancer associated with BRCA1/2 carriage. Such data will be directly useful by clinicians counseling women about ways to reduce their risk of ovarian cancer, as well as by researchers seeking prevention/intervention strategies for high-risk women.

We further anticipate providing data on treatment outcome for carriers compared to non-carriers. These data will have implications for the treatment of the disease and may suggest areas for further research in ovarian cancer treatment.

#### **REFERENCES: NONE**

#### **APPENDICES:**

IRB Approval letter from North Shore University Hospital  
Medical Record Abstraction Form implemented in TELEform.



NORTH SHORE - LONG ISLAND JEWISH HEALTH SYSTEM



**North Shore University Hospital  
Institutional Review Board**

5 Dakota Drive, Suite 306 \* Lake Success, New York 11042  
Telephone: (516)719-3100 \* Facsimile: (516)719-3110

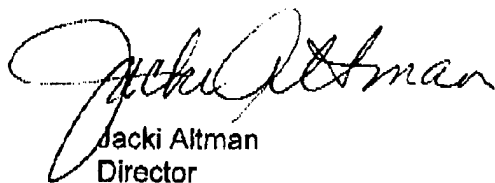
27 April 2001

Dear A. Menzin, MD:

Your proposal entitled **#00-155: Ovarian Cancer Risk and Survival** was reviewed by the Institutional Review Board on August 17, 2000. The revised Form 4, clarification that **only North Shore University Hospital at Manhasset will participate, clarification that only the following investigators will participate in the project: Drs. Menzin, Modugno, Ness, Belle, Edwards, Kant, Naus, and Ms. Gaetano; and receipt of evidence of completion of humans subjects protections programs for all investigators** you have submitted in response to their comments has/have been reviewed.

You now have **administrative approval** to begin the project. This approval will be brought to the IRB for their information and acknowledgment at their meeting on May 17, 2001. A progress report for the project is due in August 2001.

Sincerely yours,

  
Jacki Altman  
Director

## OVARIAN CANCER RISK AND SURVIVAL STUDY

## A. DATA FORM INFORMATION

A1. Study ID Number:

--	--	--	--	--	--

A2. Date Completed:

		/			/				
mo			da			yr			

A3. Completed By: \_\_\_\_\_

## B. GENERAL PATIENT INFORMATION

B1. Birth Date:

		/			/				
mo			da			yr			

B2. Height:

ft.		in.	

(Use 9's if unknown)

B3. Weight:

lbs.		

(Use 9's if unknown)

B4. At dx, subject was: ☐ premenopausal☐ perimenopausal☐ postmenopausal; if post, age at menopause:

yrs.	

☐ unknown

B5. Age at menarche:

yrs.	

(Use 9's if unknown)

**B6. History of Cancer in Mother, Father, Sister or Brother:****Ovarian:**☐ No ☐ Yes ☐ Unknown**Breast:**☐ No ☐ Yes ☐ Unknown**Colon:**☐ No ☐ Yes ☐ Unknown**Lung:**☐ No ☐ Yes ☐ Unknown**Prostate:**☐ No ☐ Yes ☐ Unknown**Other Cancer:**☐ No ☐ Yes ☐ Unknown

If Other, please specify type:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--



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**OVARIAN CANCER RISK AND SURVIVAL STUDY**

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B7. Number of Pregnancies: 

--	--

 (Use 00 if never pregnant; use 99 if unknown)

*If one or more pregnancies:*

B7.1. Number of Term Deliveries (greater than 28 weeks): 

--	--

  
(Use 99 if unknown)

B7.2. Number of Therapeutic Abortions (28 weeks or fewer): 

--	--

  
(Use 99 if unknown)

B7.3. Number of Spontaneous Abortions (28 weeks or fewer): 

--	--

  
(Use 99 if unknown)

B8. Oral Contraceptive Use: ☐ No

☐ Yes.....B8.1. Number of Months Used Over the Lifetime:

--	--	--

☐ Unknown

(Enter 999 if unknown)

B9. Non-Contraceptive Estrogen Use Only (with or without Progestin): ☐ No

☐ Yes

☐ Unknown

B9.1. Number of Months Used Over the Lifetime:

--	--	--

(Enter 999 if unknown)



--	--	--	--	--	--

## OVARIAN CANCER RISK AND SURVIVAL STUDY

### C. INITIAL DIAGNOSIS

C1. Date of Initial Diagnosis: 



 / 



 / 



 (Use 02/02/2020 if unknown)  
mo da yr

C2. Ascites: ☐ Not Present ☐ Present ☐ Unknown

#### IF ASCITES PRESENT:

C2.1. Cytology Results: ☐ Negative for cancer  
☐ Positive for cancer  
☐ Atypical, highly suspicious for cancer  
☐ Cytology not done  
☐ Cytology done, results unknown

C2.2. Amount of Ascites: ☐ Volume not measured  
☐ Volume measured, amount unknown  
☐ Volume measured

If measured: C2.3. Actual Volume (in liters):

--	--

Use 1 for less than 1 liter  
 Use 7 for 7 or more liters  
 Use 99 if unknown

### C3. Tumor Markers (Preoperative):

#### C3.1. Alphafetoprotein (AFP)

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, AFP Level

--	--	--	--	--

#### C3.2. Beta HCG

(Human chorionic gonadotropin)

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, HCG Level

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#### C3.3. CA-125

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, CA-125 Level

--	--	--	--	--

## OVARIAN CANCER RISK AND SURVIVAL STUDY

## C3.4. Carcinoembryonic antigen (CEA)

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, CEA Level

--	--	--	--	--	--

## C3.5. Hemoglobin

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, Hemoglobin Level

--	--	--	--	--	--

## C3.6. Other

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

Level if positive:

--	--	--	--	--	--

If Other, please specify:

--	--	--	--	--	--	--	--	--	--

## C4. Surgical Evaluation Performed:

## Dilatation and curettage

- ☐ No ☐ Yes ☐ Unknown

## Laparoscopy

- ☐ No ☐ Yes ☐ Unknown

## Date of Procedure

		/			/				
--	--	---	--	--	---	--	--	--	--

		/			/				
--	--	---	--	--	---	--	--	--	--

mo

da

yr

(Use 02/02/2020 if unknown)

C5. Laterality of Primary Site: ☐ right ovary☐ left ovary☐ only one side involved, left or right unspecified☐ bilateral involvement☐ laterality unknown

## C6. Histology (ICD-0):

				/	
--	--	--	--	---	--

See list of codes on opposite page

C7. Differentiation/Grade: ☐ well differentiated, Grade 1☐ moderately differentiated, Grade II☐ poorly differentiated, Grade III☐ undifferentiated☐ borderline malignancy☐ grade unknown

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**OVARIAN CANCER RISK AND SURVIVAL STUDY****C8. AJCC Stage (Pathologic)**

- C8. T-Primary Tumor:** ☐ Primary tumor cannot be assessed *(Proceed to C9.)*
- ☐ No evidence of primary tumor *(Proceed to C9.)*
- ☐ FIGO 1: Tumor limited to ovaries *(Proceed to C8.1.)*
- ☐ FIGO 2: Tumor involves one or both ovaries with pelvic extension *(Proceed to C8.2.)*
- ☐ FIGO 3: Tumor involves one or both ovaries with microscopically confirmed peritoneal implants outside the pelvis and/or regional lymph node metastasis *(Proceed to C8.3.)*

- C8.1. FIGO 1:** ☐ FIGO 1a: Tumor limited to one ovary; capsule intact, no tumor on ovarian surface, no ascites present containing malignant cells
- ☐ FIGO 1b: Tumor limited to both ovaries; capsules intact, no tumor on ovarian surface, no ascites present containing malignant cells
- ☐ FIGO 1c: Tumor limited to one or both ovaries with any of the following: capsule ruptured, tumor on ovarian surface, malignant cells in ascites or peritoneal washing

- C8.2. FIGO 2:** ☐ FIGO 2a: Extension and/or implants on uterus and/or tubes
- ☐ FIGO 2b: Extension to other pelvic tissues
- ☐ FIGO 2c: Pelvic extension (2a or 2b) with malignant cells in ascites or peritoneal washing

- C8.3. FIGO 3:** ☐ FIGO 3a: Microscopic peritoneal metastasis beyond pelvis
- ☐ FIGO 3b: Macroscopic peritoneal metastasis beyond pelvis 2 cm or less in greatest dimension
- ☐ FIGO 3c: Peritoneal metastasis beyond pelvis more than 2 cm in greatest dimension and/or regional

- C9. N-Regional Lymph Nodes** ☐ Regional lymph nodes cannot be assessed
- ☐ No regional lymph node metastasis
- ☐ Regional lymph node metastasis

- C10. M-Distant Metastasis** ☐ Presence of distant metastasis cannot be assessed
- ☐ No distant metastasis
- ☐ Distant metastasis (excludes peritoneal metastasis) (FIGO 4)

#### D. PRIMARY TREATMENT

***If no surgery or biopsy performed:***

- ☐ Never planned
- ☐ Planned, but patient refused
- ☐ Planned, but not performed for other reason (see D1.1.2.)

**D1.1.2. Specify reason:**

[illegible]

**Proceed to "Chemotherapy Regimen" on page 13**

**D2. Date of Surgery/Biopsy:**



 / 



 / 



 (Use 02/02/2020 if unknown)  
mo da yr

**D3. Type of Laparotomy:** ☐ Pfannenstiel incision  
☐ other transverse incision  
☐ low abdominal midline incision  
☐ lower and upper abdominal midline incision  
☐ other laparotomy  
☐ not applicable  
☐ unknown, not recorded

**D4. Type of Surgery:** *Unilateral salpingo-oophorectomy:*

☐ No      ☐ Yes      ☐ Unknown

**Bilateral salpingo-oophorectomy:**

☐ No      ☐ Yes      ☐ Unknown

**Total abdominal hysterectomy:**

☐ No      ☐ Yes      ☐ Unknown

**Supracervical hysterectomy:**

☐ No      ☐ Yes      ☐ Unknown

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## OVARIAN CANCER RISK AND SURVIVAL STUDY

### D4. Type of Surgery (cont'd):

#### ***Omentectomy:***

☐ No ☐ Yes ☐ Unknown

#### ***Pelvic lymph node resection:***

☐ No ☐ Yes ☐ Unknown

#### ***Small bowel resection:***

☐ No ☐ Yes ☐ Unknown

#### ***Large bowel resection:***

☐ No ☐ Yes ☐ Unknown

#### ***Other abdominal visceral resection:***

☐ No ☐ Yes ☐ Unknown

#### ***Urinary tract resection:***

☐ No ☐ Yes ☐ Unknown

#### ***Colostomy:***

☐ No ☐ Yes ☐ Unknown

#### ***Appendectomy:***

☐ No ☐ Yes ☐ Unknown

### D5. Biopsies Performed:

#### ***Cul de sac:***

☐ Negative for cancer ☐ Positive for cancer ☐ Not performed ☐ Unknown

#### ***Diaphragm:***

☐ Negative for cancer ☐ Positive for cancer ☐ Not performed ☐ Unknown

#### ***Omentum:***

☐ Negative for cancer ☐ Positive for cancer ☐ Not performed ☐ Unknown

#### ***Pericolic gutters, NOS:***

☐ Negative for cancer ☐ Positive for cancer ☐ Not performed ☐ Unknown

#### ***Bladder:***

☐ Negative for cancer ☐ Positive for cancer ☐ Not performed ☐ Unknown

#### ***Colon:***

☐ Negative for cancer ☐ Positive for cancer ☐ Not performed ☐ Unknown

#### ***Distal ureters:***

☐ Negative for cancer ☐ Positive for cancer ☐ Not performed ☐ Unknown

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**OVARIAN CANCER RISK AND SURVIVAL STUDY****D5. Biopsies Performed (cont'd):*****Genital organs:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

***Pelvic lymph nodes:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

***Para-aortic lymph nodes:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

***Rectosigmoid colon:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

***Rectum:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

***Small intestine:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

***Suspicious sites:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

***Other:***

☐ Negative for cancer      ☐ Positive for cancer      ☐ Not performed      ☐ Unknown

If Other, specify site:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

**D6. All Gross Disease Removed:** ☐ No    ☐ Yes    ☐ Unknown, not recorded

***(Includes all primary and metastatic tumor sites)***

**D7. Macroscopic Residual Disease at Conclusion of Primary Operation:**

**Abdomen:** ☐ no residual disease

☐ 1 cm or smaller

☐ >1 to 2 cm

☐ >2 cm

☐ residual NOS

**Pelvis:** ☐ no residual disease

☐ 1 cm or smaller

☐ >1 to 2 cm

☐ >2 cm

☐ residual NOS



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**OVARIAN CANCER RISK AND SURVIVAL STUDY**

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**D8. Percentage of Tumor Cytoreduction (debulking) During Primary Operation:**

- ☐ none
- ☐ less than 25%
- ☐ 25-49%
- ☐ 50-74%
- ☐ 75-99%
- ☐ 100%
- ☐ unknown, not recorded

**D9. Number of Remaining Nodules of Tumor at Conclusion of Primary Operation:**

- ☐ none
- ☐ less than 10 nodules
- ☐ 10-20 nodules
- ☐ more than 20 nodules, dissemination
- ☐ unknown, not recorded

**D10. Type of Primary Surgeon:** ☐ gynecologic oncologist

- ☐ obstetrician/gynecologist
- ☐ surgical oncologist
- ☐ general surgeon
- ☐ urologist
- ☐ fellow, resident, intern, medical student
- ☐ general practitioner
- ☐ not applicable
- ☐ unknown

[illegible]

**D12. Chemotherapy Given:** ☐ No (See D12.1.)  
☐ Yes (See D12.2.)

**D12.1. Reason:** ☐ Never planned

- ☐ **Planned, but patient refused**
- ☐ **Planned, but not performed for other reason (see D12.1.2.)**

**D12.1.2. Specify reason:**

[illegible]

**Proceed to "Radiation Therapy" on page 14**

***If chemotherapy given:***

### **D12.2. Chemotherapy Complications Leading to Toxic Death or Permanent Disability:**

- ☐ death
- ☐ disability: see D12.2.1.
- ☐ neither
- ☐ unknown

**D12.2.1. Specific chemotherapy complication leading to disability:**

[illegible]

***Proceed to "Chemotherapy Regimen" on page 13***

Study ID: \_\_\_\_\_

## OVARIAN CANCER RISK AND SURVIVAL STUDY

### D 12.3. CHEMOTHERAPY REGIMEN

*If chemotherapy given, specify:*

Code	Name	Method	Start Date	Stop Date	Complete Cycles
			-- / / --	-- / / --	
			-- / / --	-- / / --	
			-- / / --	-- / / --	
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			-- / / --	-- / / --	
			-- / / --	-- / / --	

## RADIATION THERAPY

***If no radiation therapy given:***

- ☐ Never planned
- ☐ Planned, but patient refused
- ☐ Planned, but not performed for other reason (see D13.1.2.)

[illegible]

***Proceed to D14. "Other Definitive Therapy Given"***

**D13.2. Date Treatment Began:**

mo      da      yr

(Use 02/02/2020 if unknown)

### Pelvis (with or without regional nodes)

☐ No    ☐ Yes    ☐ Unknown

### Whole Abdomen (with or without regional nodes)

☐ No    ☐ Yes    ☐ Unknown

**Other**

☐ No      ☐ Yes      ☐ Unknown

**If Other, specify:**

[illegible]

**D13.4. Date of Last Treatment:**

mo / da / yr

(Use 02/02/2020 if unknown)

**D13.5. Total Rad Dose (includes boost dose):**

--	--	--	--	--

(Use 9's if unknown)

\_\_\_\_\_

**D13.7. Radiation Therapy Complications:** ☐ No ☐ Yes ☐ Unknown

[illegible]

☐ No (See D14.1.)

**If yes, specify:**

[illegible]

***If no other therapy given:***

☐ Never planned

**○ Planned, but patient refused**

☐ **Planned, but not performed for other reason (see D14.1.2.)**

**D14.1.2. Specify reason:**

[illegible]

## OVARIAN CANCER RISK AND SURVIVAL STUDY

### DISEASE RESPONSE AND STATUS AFTER COMPLETION OF PRIMARY THERAPY

**D15. Diagnostic x-rays or scans:** ☐ Complete

- ☐ Partial
- ☐ Stable
- ☐ Progression of disease
- ☐ No primary therapy given
- ☐ Unknown, not recorded

**D16. Tumor Markers:** ☐ Complete

- ☐ Partial
- ☐ Stable
- ☐ Progression of disease
- ☐ No primary therapy given
- ☐ Unknown, not recorded

## SECOND LOOK OPERATION

### D17. Second-Look Operation after Primary Treatment:

- ☐ No
- ☐ Yes
- ☐ Unknown

***If no second-look operation performed,***

**D17.1. Reason:**

- ☐ **Never planned**
- ☐ **Planned, but patient refused**
- ☐ **Planned, but not performed for other reason (see D17.1.2.)**

**D17.1.2. Specify reason:**

[illegible]

***Proceed to "Recurrences" on page 18***

### D18. Results of Second-Look Operation:

- ☐ Negative
- ☐ Microscopically positive
- ☐ Macroscopically positive

**D19. Size of Residual Tumor at Second-Look Operation:**

- ☐ no residual disease
- ☐ 1 cm or smaller
- ☐ >1 to 2 cm
- ☐ >2 cm
- ☐ residual NOS

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**OVARIAN CANCER RISK AND SURVIVAL STUDY**

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**D20 Percentage of Tumor Cytoreduction (debulking) during Seond-Look Operation:**

- ☐ none
- ☐ less than 25%
- ☐ 25-49%
- ☐ 50-74%
- ☐ 75-99%
- ☐ 100%
- ☐ unknown

**D21. Number of Remaining Nodules of Tumor at Conclusion of Second-Look Operation:**

- ☐ none
- ☐ less than 10 nodules
- ☐ 10-20 nodules
- ☐ more than 20 nodules, dissemination
- ☐ unknown



E1. Date of Recurrence: 



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## OVARIAN CANCER RISK AND SURVIVAL STUDY

### E4. Tumor Markers:

#### Alphafetoprotein (AFP)

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, AFP Level

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#### Beta HCG

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown
- (Human chorionic gonadotropin)

If positive, HCG Level

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#### CA-125

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, CA-125 Level

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#### Carcinoembryonic antigen (CEA)

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, CEA Level

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#### Hemoglobin

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

If positive, Hemoglobin Level

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#### Other

- ☐ Negative  
☐ Positive  
☐ Not Done  
☐ Unknown

Level if positive:

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If Other, please specify:

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### F. TREATMENT FOR RECURRENCE

F1. Surgery Performed for Recurrence: ☐ No ☐ Yes ☐ Unknown

*If no surgery performed,*

#### F1.1. Reason:

- ☐ Never planned  
☐ Planned, but patient refused  
☐ Planned, but not performed for other reason (see F1.1.2.)

#### F1.1.2. Specify reason:

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*Proceed to F4. "Chemotherapy for Recurrence"*

## OVARIAN CANCER RISK AND SURVIVAL STUDY

F2. Second-Look Cytoreduction (debulking): ☐ No ☐ Yes ☐ Unknown

*If no Cytoreduction performed, or if unknown, proceed to F3. "Palliative Surgery" on page 21  
If Cytoreduction was performed, proceed to F2.1.*

*If Yes:*

F2.1. Percentage of Tumor Cytoreduction (debulking):

- ☐ none
- ☐ less than 25%
- ☐ 25-49%
- ☐ 50-74%
- ☐ 75-99%
- ☐ 100%
- ☐ unknown

F2.2. All Gross Disease Removed: ☐ No ☐ Yes ☐ Unknown

*(Includes all primary and metastatic tumor sites)*

F2.3. Macroscopic Residual Disease:

Abdomen:

- ☐ no residual disease
- ☐ 1 cm or smaller
- ☐ >1 to 2 cm
- ☐ >2 cm
- ☐ residual NOS
- ☐ unknown

Pelvis:

- ☐ no residual disease
- ☐ 1 cm or smaller
- ☐ >1 to 2 cm
- ☐ >2 cm
- ☐ residual NOS
- ☐ unknown

F2.4. Number of Remaining Nodules of Tumor:

- ☐ none
- ☐ less than 10 nodules
- ☐ 10-20 nodules
- ☐ more than 20 nodules, dissemination
- ☐ unknown, not recorded

## OVARIAN CANCER RISK AND SURVIVAL STUDY

**F2.5. Response/Disease Status:**

- ☐ negative for residual tumor
- ☐ positive for residual tumor
- ☐ unknown

**F3. Palliative Surgery:** ☐ No (Proceed to F3.1.)

- ☐ **Yes (planned or given)** *(Proceed to F3.2.)*

***If no palliative surgery,***

**F3.1. Reason:**

- ☐ Never planned
- ☐ Planned, but patient refused
- ☐ Planned, but not performed for other reason (see F3.1.2.)

**F3.1.2. Specify reason:**

[illegible]

**Proceed to F4., "Chemotherapy for Recurrence" on page 22**

***If palliative surgery planned or given:***

**F3.2 Surgery Performed:**

- **intestinal resection**
- **intestinal bypass**
- **inoperable, no surgery**

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**OVARIAN CANCER RISK AND SURVIVAL STUDY**

F4. Chemotherapy Given for Recurrence: ☐ No (See F4.1.)  
☐ Yes (See F4.2.)

*If no chemotherapy given,*

**F4.1. Reason:**

- ☐ Never planned  
☐ Planned, but patient refused  
☐ Planned, but not performed for other reason (see F4.1.2.)

**F4.1.2. Specify reason:**

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*Proceed to "Radiation Therapy for Recurrence" on page 24*

*If chemotherapy given,*

**F4.2.. Chemotherapy Complications Leading to Toxic Death or Permanent Disability:**

- ☐ death  
☐ disability: see F4.2.1.  
☐ neither  
☐ unknown

**F4.2.1. Specific chemotherapy complication leading to disability:**

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*If chemotherapy given for recurrence, see F 4.3. "Chemotherapy Regimen for Recurrence" on page 23*

Study ID: \_\_\_\_\_

## OVARIAN CANCER RISK AND SURVIVAL STUDY

### F 4.3. CHEMOTHERAPY REGIMEN FOR RECURRENCE

*If chemotherapy given, specify:*

Code	Name	Method	Start Date	Stop Date	Complete Cycles
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			-- / / --	-- / / --	
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## RADIATION THERAPY FOR RECURRENCE

☐ Yes (See F5.2.)

***If no radiation therapy given,***

**F5.1. Reason:**

- ☐ **Never planned**
- ☐ **Planned, but patient refused**
- ☐ **Planned, but not performed for other reason (see F5.1.2.)**

**F5.1.2. Specify reason:**

[illegible]

***Proceed to "Status at Last Contact" on page 25***

***If radiation therapy given, specify:***

F5.2. Date Treatment Began: 



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 (Use 02/02/2020 if unknown)

### F5.3. Sites Irradiated:

**Pelvis (with or without regional nodes)**

- ☐ No    ☐ Yes    ☐ Unknown

### Whole Abdomen (with or without regional nodes)

- ☐ No    ☐ Yes    ☐ Unknown

**Other**

- ☐ No    ☐ Yes    ☐ Unknown

**If Other, specify:**

[illegible]

**F5.4. Date of Last Treatment:**



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 (Use 02/02/2020 if unknown)  
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**F5.6. Radioactive Colloid Administration:** ☐ No ☐ Yes ☐ Unknown

**F5.7. Radiation Therapy Complications:** ☐ No ☐ Yes ☐ Unknown

**If yes, specify:**

[illegible]

**G. STATUS AT LAST CONTACT**

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(Use 02/02/2020 if unknown)

**G2. Patient Status:**

☐ **alive**

☐ deceased

***If deceased, specify:***

**G2.1. Date of Death:**

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(Use 02/02/2020 if unknown)

## G2.2 Autopsy Findings:

☐ no evidence of ovarian cancer

☐ ovarian cancer present

☐ not done

- findings unknown

**G3. Cancer Status:**

☐ no evidence of ovarian cancer

☐ ovarian cancer present at last contact

☐ ovarian cancer status unknown



## OVARIAN CANCER RISK AND SURVIVAL STUDY

## POST-CHEMOTHERAPY CA-125 VALUES

Date of Blood Draw:

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CA-125

☐ Negative ☐ Positive☐ Negative ☐ Positive☐ Negative ☐ Positive☐ Negative ☐ Positive☐ Negative ☐ Positive☐ Negative ☐ Positive☐ Negative ☐ Positive☐ Negative ☐ Positive

CA-125 Level

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Use 02/02/2020 if unknown